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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,740	06/23/2000	Markus Pompejus	BGI-121CP	4954

959 7590 09/27/2002

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/27/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/606,740

Applicant(s)
Pompejus et al.

Examiner
Christian L. Fronda

Art Unit
1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1652

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17, drawn to an isolated nucleic acid, vector, host cell, and method of making a polypeptide, classified in class 435, subclass 69.1.
 - II. Claims 18-24, drawn to an isolated polypeptide, classified in class 514, subclass 2.
 - III. Claims 25-33, drawn to a method for producing a fine chemical comprising culturing a cell containing a vector, classified in class 435, subclass 41.
 - IV. Claim 34 drawn to a method for producing a fine chemical comprising culturing a cell whose genomic DNA has been altered by inclusion of a nucleic acid, classified in class 435, subclass 41.
 - V. Claim 35, drawn to a method for diagnosing the presence or activity of *Corynebacterium diphtheriae* in a subject comprising detecting the presence of a nucleic acid sequence in the subject, classified in class 435, subclass 6.
 - VI. Claim 36, drawn to a host cell comprising a nucleic acid molecule wherein the nucleic acid molecule is disrupted, classified in class 435, subclass 252.3.
 - VII. Claim 37, drawn to a host cell comprising a nucleic acid molecule wherein the nucleic acid molecule comprises one or more nucleic acid modifications, classified in class 435, subclass 252.3.
 - VIII. Claim 38, drawn to a host cell comprising a nucleic acid molecule wherein the regulatory region of the nucleic acid molecule is modified relative to the wild-type regulatory region of the molecule, classified in class 435, subclass 252.3.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, and VI-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The products of Groups I, II, and VI-VIII are each independent chemical entities and require different literature searches.

Inventions of Groups III-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The methods of Groups III-V are distinct both physically and functionally; require different process steps, reagents, and parameters; and produce different products.

Art Unit: 1652

Invention of Groups II and VI-VIII are unrelated to the processes of Groups III-V. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the processes of Groups III-V do not require the product of Groups II and VI-VIII.

Invention of Group I is unrelated to the process of Group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The process of Group IV does not require the product of Group I.

Inventions I and (III and V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the polynucleotide in a recombinant process to make a polypeptide.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their divergent subject matter, restriction for examination purposes as indicated is proper.

3. The claims are generic to a plurality of disclosed patentably distinct species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

In the invention of Groups I-VIII, the species are each of the sequences listed in Tables 1-4, Appendix A and B, and SEQ ID NOS: 1-1156. If any group is elected, Applicants must elect only one species for examination.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

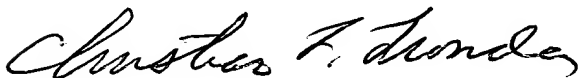
4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

Art Unit: 1652

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. The Examiner can be contacted Monday-Friday from 8:30AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.



Christian L. Fronda
Patent Examiner
Technology Center 1600
Art Unit 1652